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Supporting applicants in the area of regulated products (REPRO)

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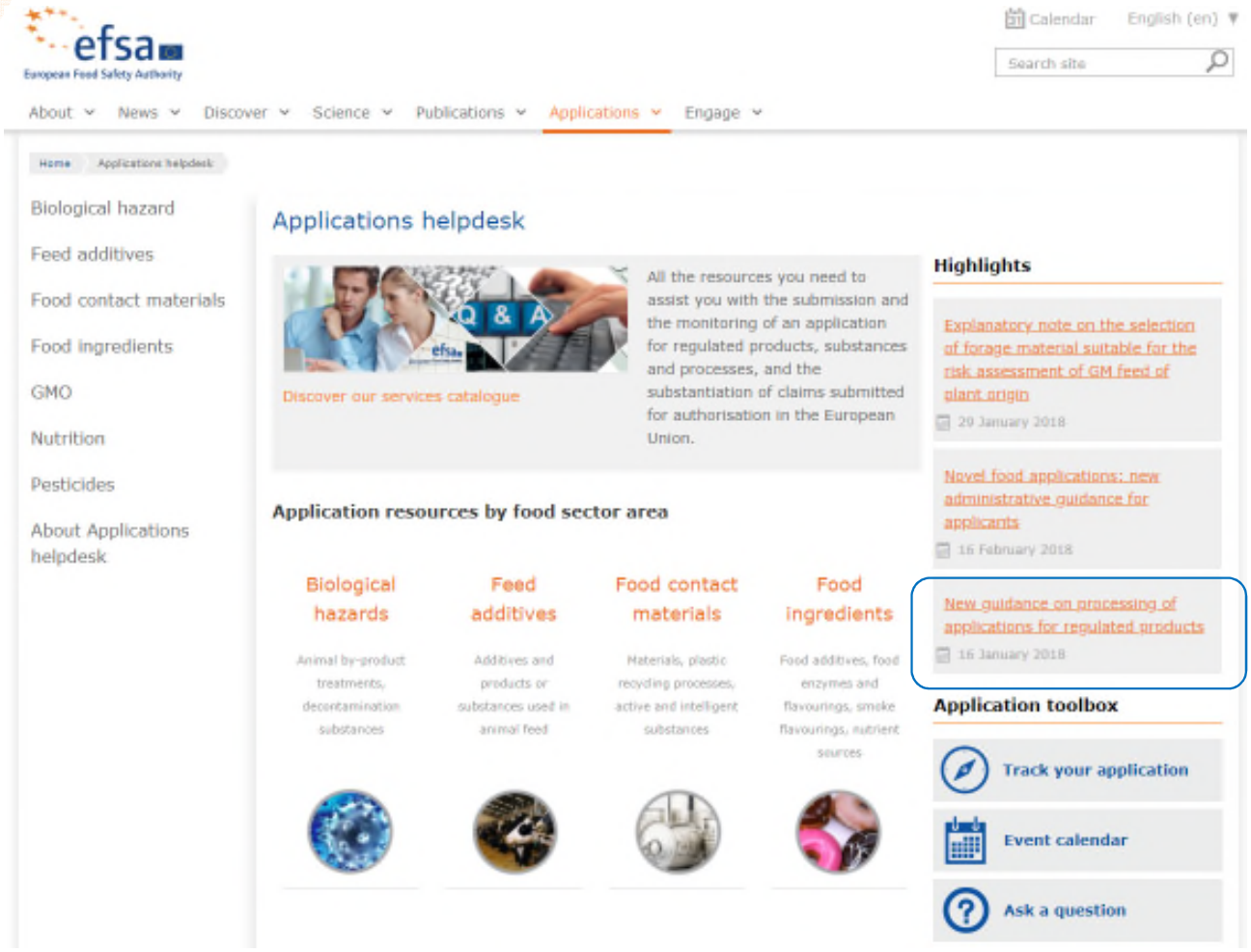
Trusted science for safe food

efsa
European Food Safety Authority

Engagement and support to applicants

- REPRO Administrative guidance
- Catalogue of services
- SME initiatives

Administrative guidance on the processing of applications




TECHNICAL REPORT

Administrative guidance for the processing of applications for regulated products

European Food Safety Authority

Abstract

EFSA is continuously striving to enhance its support initiatives in the area of regulated products, enhancing a customer-oriented approach, supporting applicants during the whole life-cycle of the applications for regulated products. EFSA is registering around 500 mandates on applications for regulated products on a yearly basis governed by more than 34 different EU Directives and Regulations and following 20 workflows. In this context, EFSA developed this administrative guidance on the principles followed to process applications for regulated products in order to enhance transparency and understanding, and to ensure that a coherent, sound, systematic and efficient process is carried out, in compliance with each sectorial legislation. This administrative guidance for the processing of applications for regulated products describes in a harmonised way: the general workflow of applications, the key steps of the scientific risk assessment process, the mechanism of suspension/extension of the scientific assessment, its restart, the conclusion of the scientific risk assessment process and the publication of the scientific output. This administrative guidance does not apply to pesticides processes and to the re-evaluation of food additives which will be integrated in the document in a next version. EFSA will update the administrative guidance for the processing of applications for regulated products, when needed, in line with amendments to the legal acts, to relevant changes to guidance documents and/or approaches, and according to the experience gained in handling and assessing applications. Applicants are advised to always consult the latest published version of this document available on the EFSA website.

Key words: Application for regulated products, EFSA scientific outputs, mandates, sectorial legislation, processes, risk/scientific assessment, workflows

Requestor: European Food Safety Authority

Question number: EFSA-Q-2015-00504

Correspondence: applesk.applications@efsa.europa.eu

The Guidance

Objectives

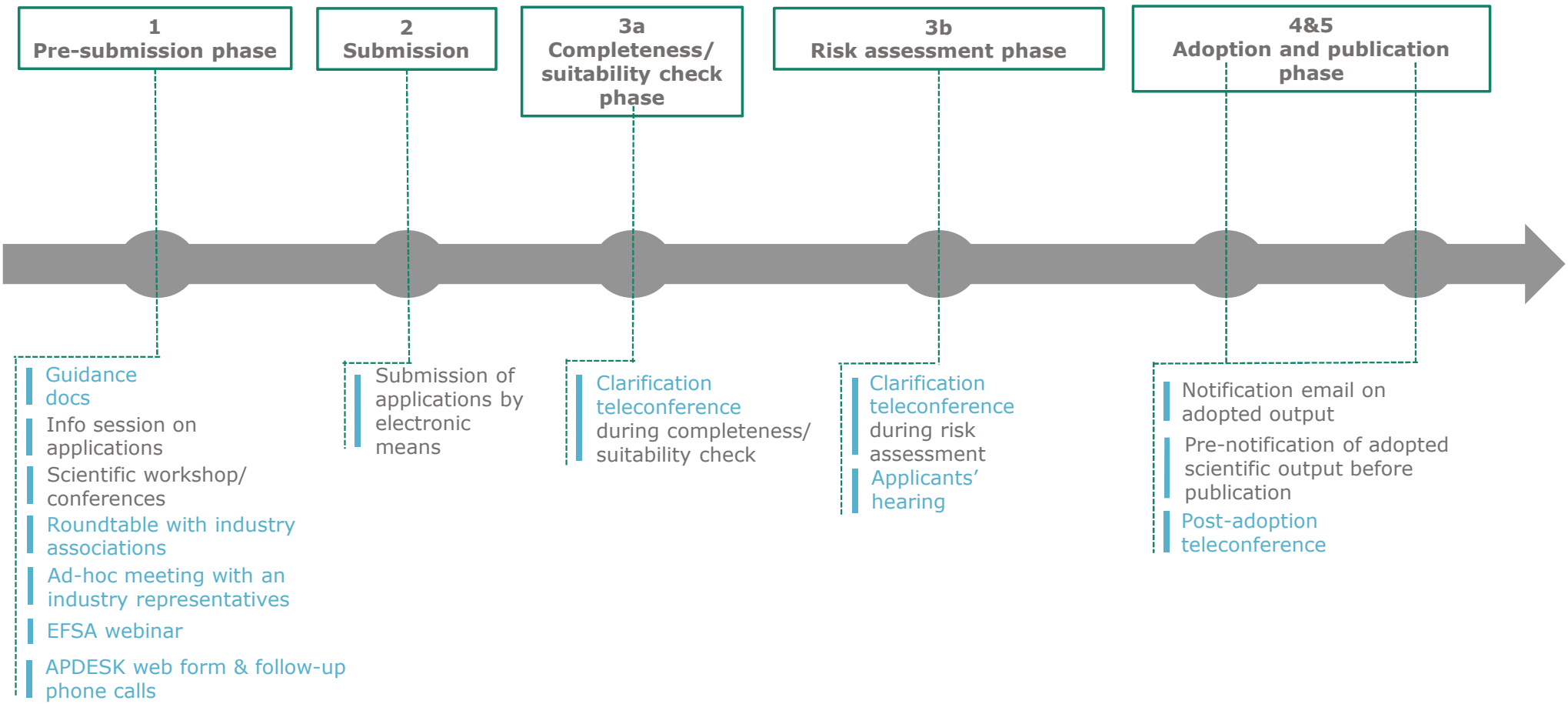
- To describe and harmonise the processing of applications for regulated products by EFSA

- To enhance **transparency**, understanding and ensure systematic and **efficient process**

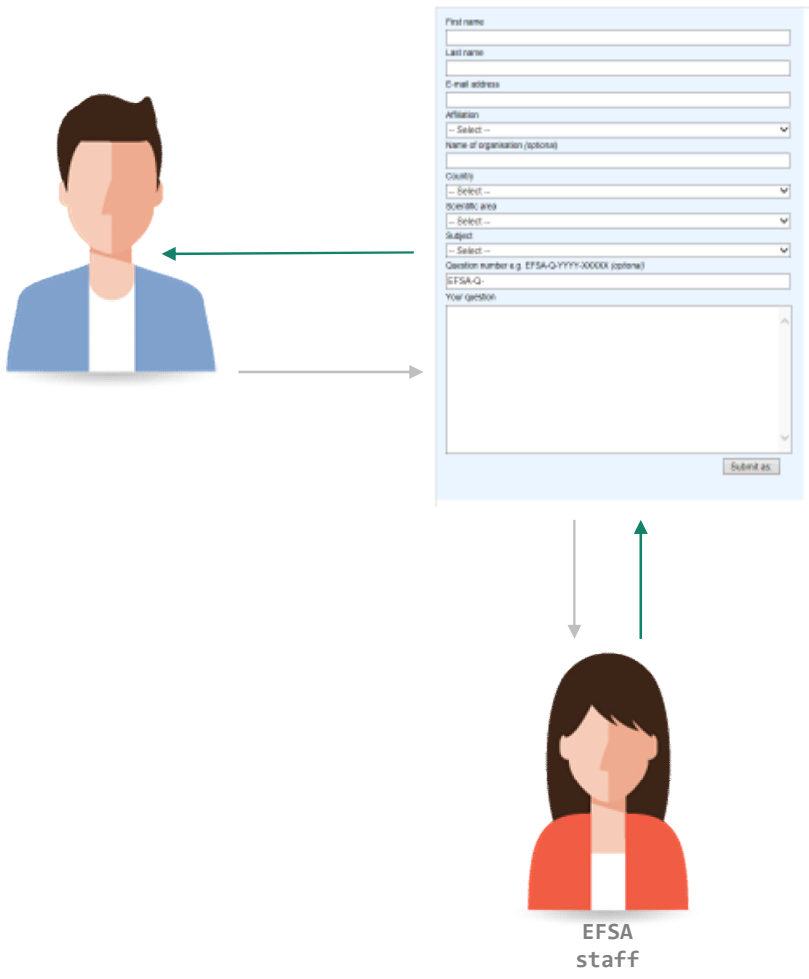
Outside scope (to be included in next revision): pesticides processes, re-evaluation of food additives

To be read in conjunction with each **sectorial legislation** (applicable legal act).

Catalogue of services



APDESK web form



Any stakeholder interested on regulated products

Front office and support desk on regulated products related matters

EFSA staff, web form requestor

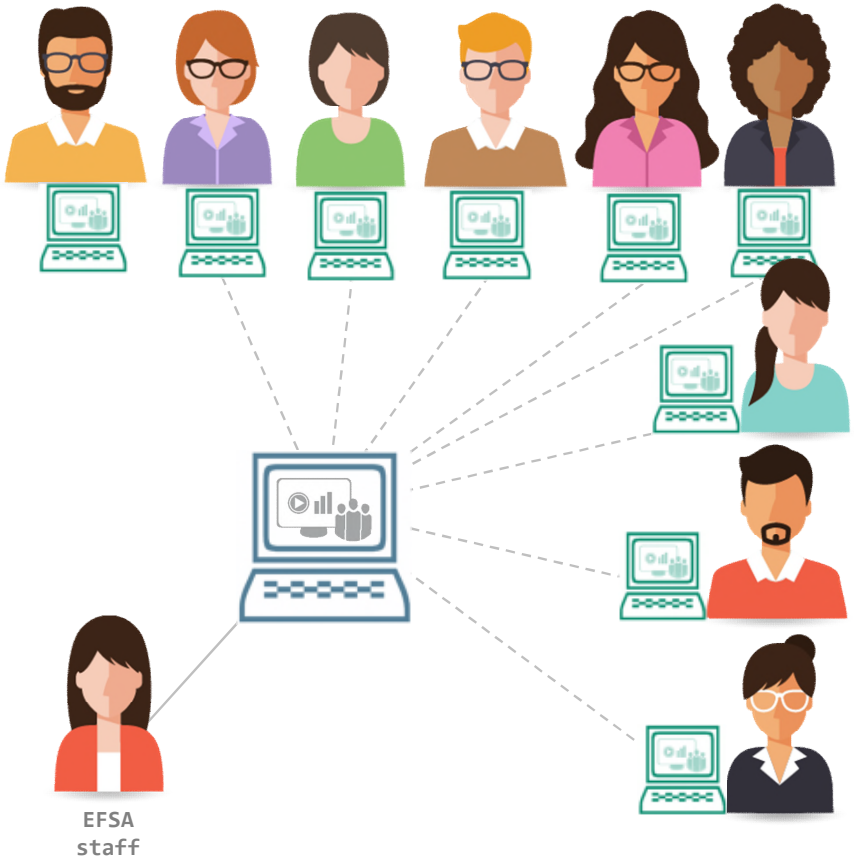
Responses to web form requests are provided within 15 working days

Fill-in the web form available on EFSA's Applications web section

Administrative and scientific issues, EU regulatory framework, guidance documents requirements, procedural steps, status of specific applications

Individual answer to requests within 15 working days from receipt

EFSA webinars



EFSA units

Online event to exchange views and enhance an open dialogue on practical scientific and administrative issues as well as tools

EFSA experts of Working Groups/Panels, EFSA staff, EC, Online registrants

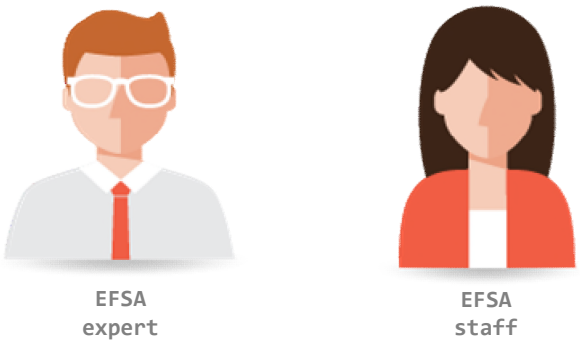
30 minutes, 1hour, 2 hours

Online registration once public registration to a webinar is opened on EFSA website

Methodological and procedural aspects, scientific requirements, approach(es) unique to particular scientific areas

Final agenda, presentations, post-event summary, webinar recording

EFSA guidance documents



EFSA units

Production, revision and updates of EFSA's technical and administrative documents to explain administrative or scientific requirements

They can include: examples or case studies, data requirements, list of scientific evidence.
Explanatory notes are supplementary documents including key principles and examples of good studies/reporting

New guidance documents (technical or administrative) published on the EFSA website

Roundtable with industry associations

EFSA

Annual meeting on food and feed regulated products to increase transparency and engagement

EFSA staff, EC, industry associations

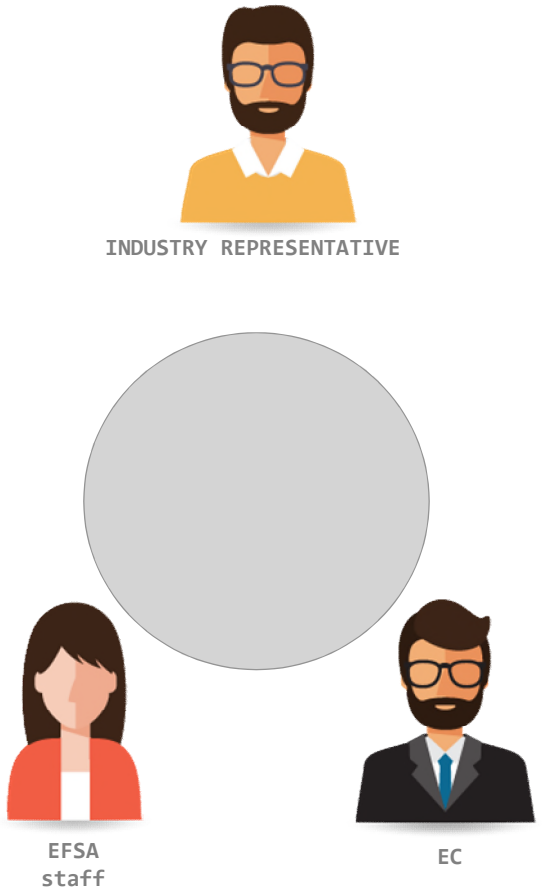
Half a day

Upon invitation by EFSA

Administrative, scientific, managerial, communication issues and challenges linked to applications for regulated products

Final agenda, all presentations list of participants, post-event summary

Ad-hoc meeting with industry representatives



- Industry representatives
- Exchange information and views on food and feed regulated product applications
- EFSA staff, EC, industry representative
- 1 hour up to 4 hours (indicative timeline)
- Contact the scientific unit
- Methodological and procedural aspects, scientific requirements, approach(es) unique to particular scientific areas
- Final agenda, all presentations, list of participants

Clarification teleconference during CC / SC

Applicant / APDESK

Telephone conference to clarify any outstanding issues during the completeness/suitability check (CC) phase

EFSA APDESK staff, applicant

30 minutes

An applicant upon reception of an EFSA letter requesting missing information or at any time during the CC phase

Clarify administrative and scientific rationale of individual questions during CC, ensure understanding of the questions to be answered by the applicant, clarify outstanding issues

EFSA e-mail acknowledging that the teleconference took place indicating date and duration

Clarification teleconference during RA

Applicant

Telephone conference to clarify a request for additional information sent by EFSA during the risk assessment (RA) phase

EFSA REPRO units staff, applicant

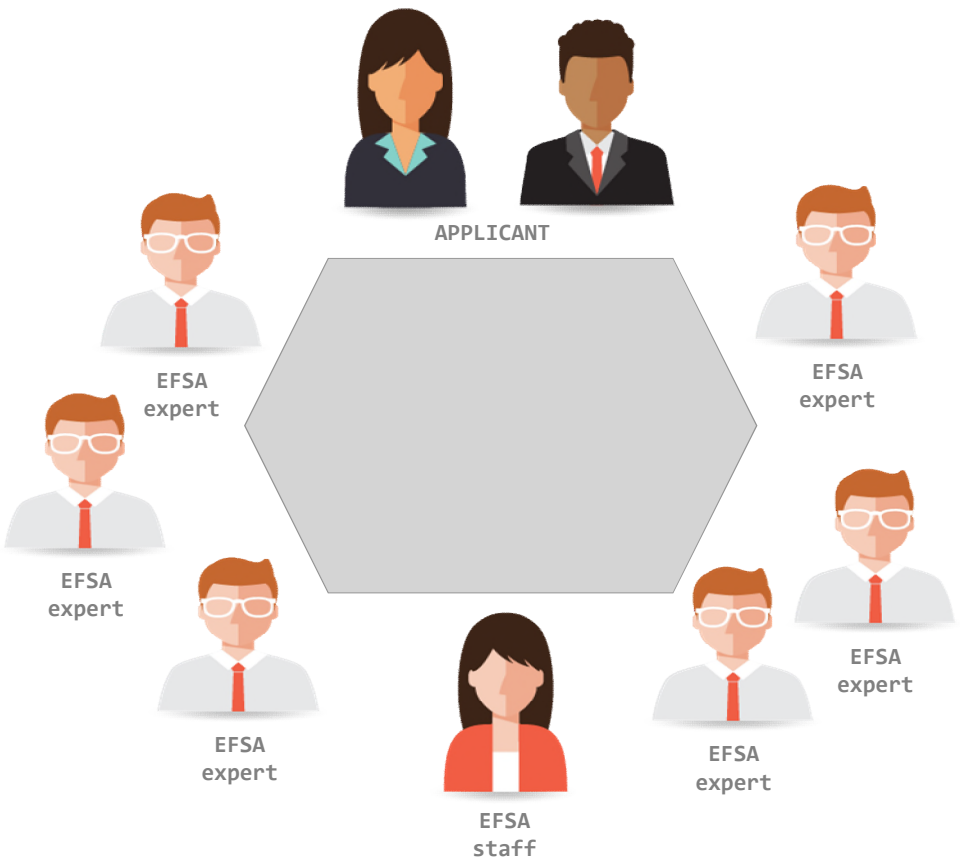
1 hour (indicative timeline)

An applicant upon reception of an EFSA letter requesting additional information

Clarify the scientific rationale of individual questions raised during RA, ensure understanding of the questions to be answered. It does not provide pre-assessment on upcoming responses

EFSA e-mail acknowledging that the teleconference took place indicating date and duration

Applicants' hearing



EFSA invites the applicant to attend a specific agenda item of working groups or Panel meetings

An applicant is invited to an applicants' hearing to answer question raised by the EFSA working groups and Panels experts

EFSA experts, EFSA staff, applicant

2 hours maximum

EFSA's working groups and/or Panels members

Clarify additional data or supplementary information provided when considered not appropriate or unclear, or to clarify any outstanding issues on the application

Participation to an applicants' hearing is reported in the meeting minutes published on EFSA website. EFSA staff sends a follow-up letter to the applicant to ensure mutual understanding

Post-adoption teleconference

Applicant

Telephone conference on adopted scientific output to present the content of the final scientific output, as expressed by the Panels and/or EFSA

EFSA staff, applicant, EC

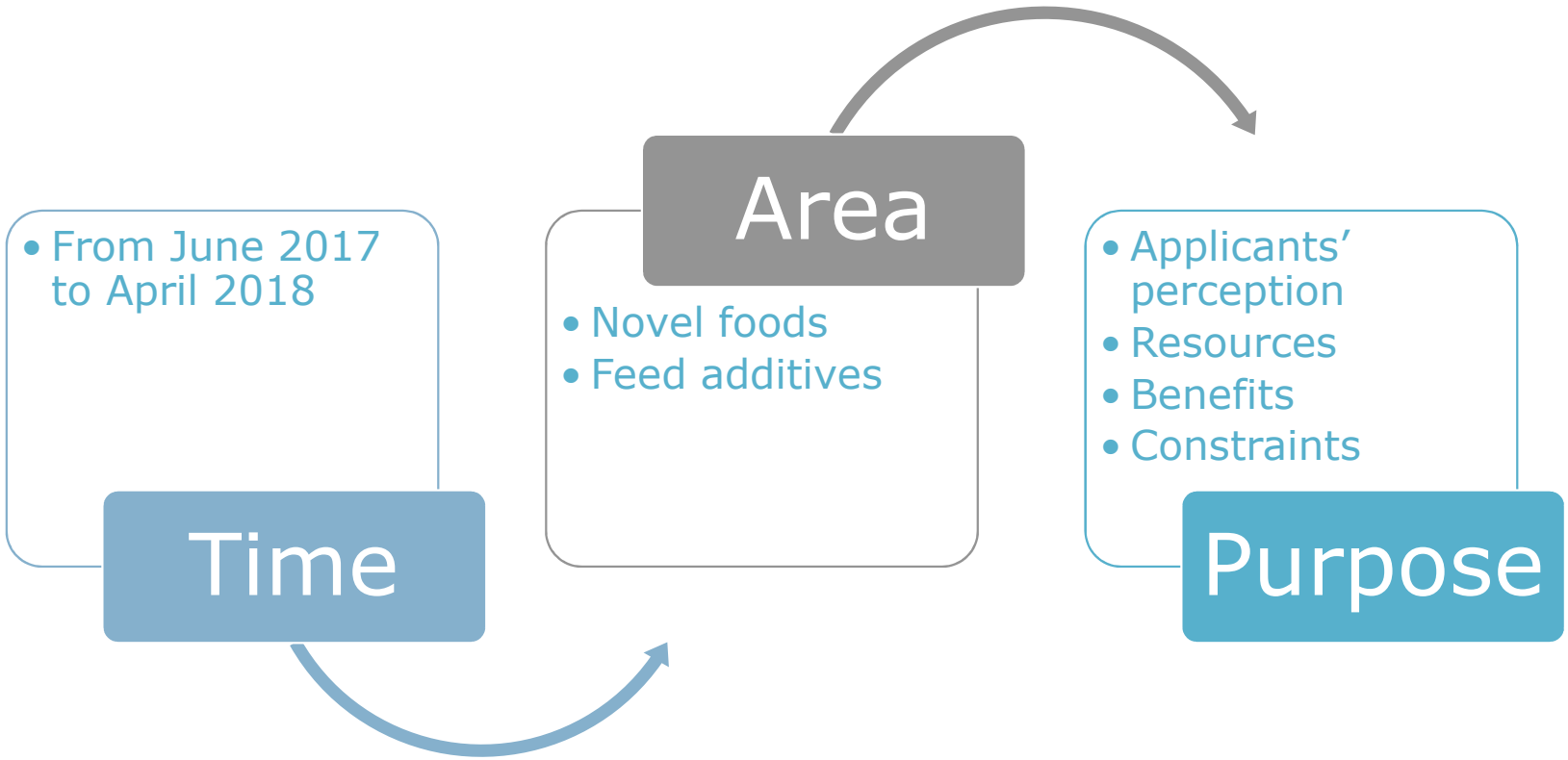
2 hours

An applicant who has filed an application to EFSA for which an EFSA scientific output was published

Explain the scientific rationale of the final output from the Panel and/or EFSA, clarify recommendations (if applicable), clarify the sources of evidence and factors that influenced the outcome. Such teleconference do not provide any scientific advice for future submissions

Follow-up letter including main points of discussion to keep track of what has been discussed

SME initiatives
Pre-submission administrative check



Pre-submission administrative check

SMEs **confirmed** that:

- The teleconference was **useful**
- The **support** provided by the EFSA staff before the teleconference was **helpful**
- EFSA staff **carefully explained** how to improve the dossier and **addressed all questions** raised during the teleconference
- Applicant felt supported by EFSA in the preparation of the dossier
- All companies consulted would **recommend this service** to other SMEs

New initiatives for SMEs

1. Administrative support: front line office for SMEs

2. Monitoring of applications submitted by SMEs

3. Fast processing of queries submitted by SMEs

4. Establish EFSA register of SMEs

Useful links

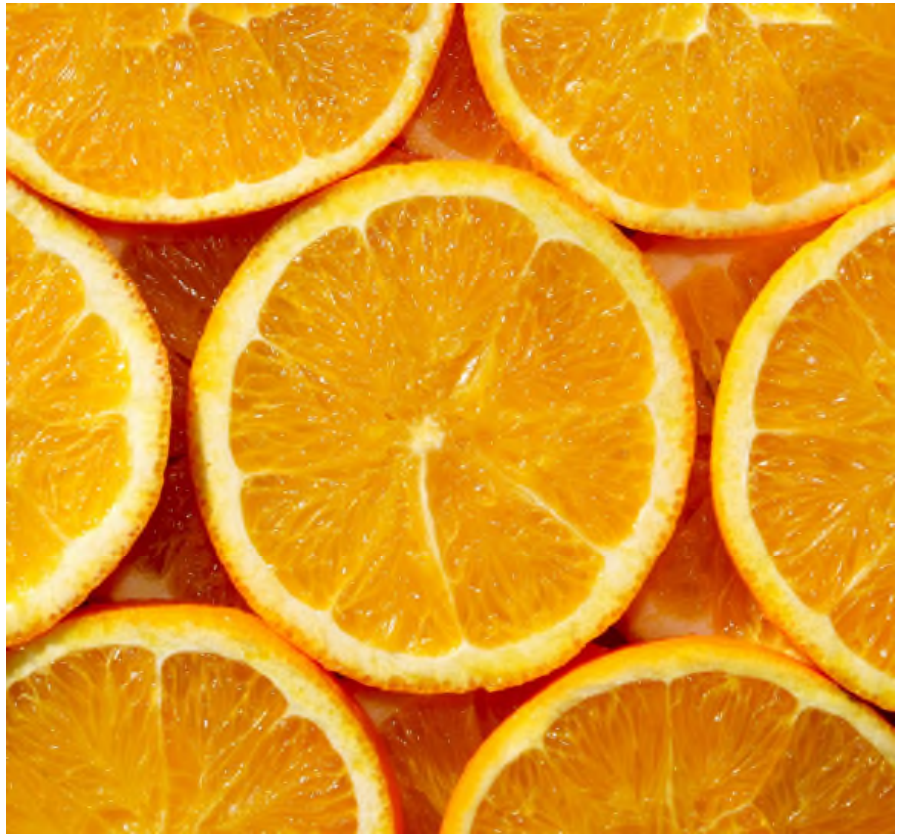
- Do you want to consult the **Catalogue**? Go to the EFSA website

  APDESK webinar available here

- Do you want to check the **administrative guidance**? Look it up on the EFSA website

- Are you looking for information on **regulated products**? Check the Applications section

- Do you **have a question** on applications? Contact EFSA via the APDESK webform



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